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NOTICE OF INDEPENDENT REVIEW DECISION

DATE NOTICE SENT TO ALL PARTIES:
Apr/21/2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Compound cream Ketoprofen 10%, Clonidine 0.2%, Gabapentin 6%, Imiprimine 3%, Lidocaine 2%, Mefenamic acid 3% 240 mg tube (6 refills)

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Board Certified Anesthesiologist

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

[X] Upheld (Agree)

[ ] Overturned (Disagree)

[ ] Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for <u>each</u> health care service in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is a female who originally sustained an injury on xx/xx/xx when she fell. The patient underwent prior fusion at the ankle with subsequent development of chronic regional pain syndrome. The patient received a spinal cord stimulator in 10/09. The clinical history noted multiple injections including both trigger point injections and Botox injections. Prior medication history included Lexapro which was beneficial. The patient had also been utilizing a topical compounded medication as far back as 05/13. The patient reported some relief of neuropathic pain with this compounded medication. Further Botox injections were noted in 2013. The patient began to have problems with her previous spinal cord stimulator in 12/13 for which the patient was recommended for a new unit. Medications as of 01/16/14 included Lexapro Lyrica Robaxin and hydrocodone along with topical medications. The patient received a replacement spinal cord stimulator on 03/11/14. The most recent evaluation for the patient on 03/20/14 indicated that the patient had good response with the new spinal cord stimulator at 100% improvement. The compounded medication request for this patient was denied by utilization review on 02/24/14 as there were other medications that could potentially address the neuropathic symptoms. There was also no FDA approval for majority of the components recommended in the compounded medication. The requested compounded topical medication was again denied by utilization review on 03/26/14 as a majority of the components did not have FDA approval for transdermal use and there was insufficient evidence supporting re-initiation of the compounded medications.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The patient has been followed for a long history of neuropathic pain secondary to chronic regional pain syndrome. These symptoms have been controlled with a spinal cord stimulator multiple Botox injections oral medications including Lexapro and a compounded medication. From the clinical records it is unclear to what extent the topical medication has been effective for the symptoms. The most recent clinical notes indicate that the primary pain response has been to the replaced spinal cord stimulator for which the patient reported 100% improvement. At this time there is no indication of any ongoing uncontrolled neuropathic pain that would require the re-initialization of a compounded medication of which most of the components recommended for the patient are not approved by the FDA for transdermal use. The majority of the components requested for this patient would still be considered experimental/investigational by the clinical literature. Therefore it is the opinion of this reviewer that medical necessity is not established for the requested compounded medication at this time. As such the prior denials are upheld.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

[ ] ACOEM-AMERICA COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE

[ ] AHCPR-AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES

[ ] DWC-DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

[ ] EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN

[ ] INTERQUAL CRITERIA

[X] MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

[ ] MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

[ ] MILLIMAN CARE GUIDELINES

[X] ODG-OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

[ ] PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR

[ ] TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS

[ ] TEXAS TACADA GUIDELINES

[ ] TMF SCREENING CRITERIA MANUAL

[ ] PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

[ ] OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)